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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590 10/31/2003

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EXAMINER

BUNNER, BRIDGET E

ART UNIT PAPER NUMBER

1647

DATE MAILED: 10/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/801,115	MA ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-36,38-51,54,55,57-60,62 and 63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34-36,38-51 and 54-55, 57-59, 63 is/are allowable.
- 6) ☒ Claim(s) 60 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11/30/02</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendments of 06 September 2003 has been entered in full. Claims 34, 42, 45, 48, 51, 54-55, 58, 60, 62, and 63 are amended. Claims 52, 56, and 61 are cancelled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 34-36, 38-51, 54-55, 57-60 and 62-63 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

1. The objection to claims 51 and 38 at pg 4 of the previous Office Action (15 July 2003) is *withdrawn* in view of the amended claims (06 September 2003).
2. The rejection of claims 51-52, 54-59, and 63 under 35 U.S.C., first paragraph (enablement) as set forth at pg 4-6 of the previous Office Action (15 July 2003) is *withdrawn* in view of the amended claims (06 September 2003).
3. The rejection of claims 51-52 and 54-63 under 35 U.S.C., first paragraph (written description) as set forth at pg 8-10 of the previous Office Action (15 July 2003) is *withdrawn in part* in view of the amended claims (06 September 2003).
4. The rejection of claims 34-36, 39-46, 48-50, 51-52, and 54-63 under 35 U.S.C. § 103(a) as set forth at pg 10-12 of the previous Office Action (15 July 2003) is *withdrawn* in view of the amended and cancelled claims (06 September 2003).
5. The information disclosure statement (IDS) submitted on 30 November 2002 is being considered by the examiner. Brantschen et al. and Marshall et al. were received by the PTO with the Response of 06 September 2003.

Claim Rejections - 35 USC § 112

6. Claims 60-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The basis for this rejection is set forth at pg 7-8 of the previous Office Action (15 July 2003).

Specifically, the claims are directed to a method of producing a polypeptide fragment comprising introducing the vector of claim 55 into a host cell, and expressing from the host cell or extracellular media the polypeptide fragment encoded by said cDNA. The claims also recite a vector and host cell.

Applicant's arguments (06 September 2003), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant asserts that the polypeptide produced by the fragment of a polynucleotide of SEQ ID NO: 1 and may or may not be a chemokine like factor polypeptide and therefore, have amended claim 60 accordingly. Applicant contends that the amended claim 60 merely further defines a method of using a vector containing the polynucleotide fragment of claim 51 with a host cell to express the polypeptide encoded by the polynucleotide fragment of claim 51.

Applicant's arguments have been fully considered but are not found to be persuasive. The Examiner acknowledges that polynucleotide fragments may be employed as probes for the polynucleotide of SEQ ID NO: 1. However, the specification does not teach any methods or working examples that produce a CKLF1 polypeptide by introducing a vector containing any polynucleotide fragment of SEQ ID NO: 1 into a host cell and expressing the polypeptide encoded by the cDNA from the host cell. Undue experimentation would be required of the

Art Unit: 1647

skilled artisan to generate the infinite number of polynucleotide fragments and polypeptide derivatives recited in the claims and screen the same for activity. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites.

Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

(Please note that this issue could be overcome by cancelling claims 60 and 62).

7. Claims 60 and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is set forth at pg 8-10 of the previous Office Action (15 July 2003).

Art Unit: 1647

Specifically, the claims are directed to a method of producing a polypeptide fragment comprising introducing the vector of claim 55 into a host cell, and expressing from the host cell or extracellular media the polypeptide fragment encoded by said cDNA. The claims also recite a vector and host cell.

Applicant's arguments (06 September 2003), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant asserts that the rejection of the claims as failing to comply with the written description requirement is traversed by the claim amendments.

Applicant's arguments have been fully considered but are not found to be persuasive. The specification of the instant application does not teach functional or structural characteristics of the all claimed polynucleotide fragments in the context of a cell or organism. The description of one functional chemokine-like polynucleotide species (SEQ ID NO: 1) and one polypeptide species (SEQ ID NO: 2) is not adequate written description of an entire genus of functionally equivalent polynucleotides and polypeptides which incorporate all fragments. The skilled artisan cannot envision the polypeptide fragments of the encompassed method, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. The specification's general discussion of making and screening for variants (pg 7-9) constitutes an invitation to experiment by trial and error. Such does not constitute an adequate written description for the fragments encompassed by the claimed method.

(Please note that this issue could be overcome by cancelling claims 60 and 62).

Conclusion

Claims 34-36, 38-51, 54-55, 57-59, 63 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

Elizabeth C. Kemmerer

BEB
Art Unit 1647
22 October 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER